K070795
p1/4

510(k) Summary

AUG 3 1 2007

A. Device Name

The name of this device is the SphygmoCor® Cardiovascular Management System (CvMS). The Common/Classification Name: Blood Pressure Computer as classified per 21 C.F.R. § 870.1110

B. Submitter

AtCor Medical Pty Ltd.
West Ryde Corporate Centre
1059-1063 Victoria Road, Suite 11
West Ryde, NSW 2114
Australia

011-61-2-9874-8761
011-61-2-9876-9022 (Fax)
Contact: Ross Harricks, CEO

C. Legally Marketed Predicate Devices

The CvMS is substantially equivalent to the SphygmoCor SCOR-Px (K012487).

The CvMS's Heart Rate Variability (HRV) feature is substantially equivalent to:

1. Boston Medical Technologies' "BMT Anscore Health Management System" and its variations (K991831, K993875, and K010955);
2. QMed, Inc.'s "Monitor One NDX" HRV analysis function (K972991); and
3. Spacelabs, Inc.'s "Heart Rate Variability Software Option" (K950779).

B. Device Description

The CvMS is a modified version of the SphygmoCor Px (K012487). Like its predecessor, the CvMS is a computerized tool for the assessment of a range of central arterial vascular parameters, including blood pressure, by peripheral pulse wave detection, calibration, and analysis that can be derived from the calibrated peripheral pressure waveform. The CvMS is used with a tonometer over the radial artery, and is calibrated with a standard blood pressure cuff measurement. The CvMS is intended for use on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. In addition, the CvMS incorporates an option to enable users to measure Heart Rate Variability (HRV) in response to controlled exercises.

The CvMS is made up of three primary components: 1) a proprietary signal processing electronics module; 2) proprietary software; and 3) a Millar Micro-Tip Pulse Transducer tonometer (Millar tonometer). The Millar tonometer is manufactured by Millar Instruments, Inc. (Millar) and was cleared by the U.S. Food and Drug Administration (FDA) for marketing on July 2, 2002 (K013205), as a finished device, independent of its use as a component of the CvMS.

One notable new feature incorporated into the CvMS is the addition of the capability to non-invasively measure Heart Rate Variability (HRV) data. The CvMS measures the variability in intervals between R waves ("R-R intervals") on a continuous beat-to-beat basis for a period of time to provide HRV data and to use standard analysis procedures to provide stable and evoked measures of HRV in response to certain controlled exercises. The CvMS is also capable of providing Central Blood Pressure (PWA) and Pulse Wave Velocity (PWV) measurements.

The CvMS system is available in three different configuration options based upon these measurement capabilities. These options allow the user to select a measurement system that suits their particular clinical needs. These configuration options include:

1. SphygmoCor Px Pulse Wave Analysis (PWA) System (Px);
2. SphygmoCor Vx Pulse Wave Velocity (PWV) System (Vx); and
3. SphygmoCor Hx Heart Rate Variability (HRV) System (Hx).
4. AtCor is not seeking clearance for the SphygmoCor Mx Pulse Wave Monitoring (PWM) System configuration in this 510(k) submission.

All measurements may be stored and viewed on an attached computer which is attached to the CvMS's signal processing electronics module via a standard USB cable. The patient study reports are displayed on an attached computer.

C. Indications for Use

The SphygmoCor® Cardiovascular Management System (CvMS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The CvMS is used with a tonometer over a radial artery calibrated with a standard cuff blood pressure measurement. It is to be used on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

The CvMS Heart Rate Variability (HRV) option is intended for use in obtaining HRV measurements in response to controlled exercises.

D. Substantial Equivalence Summary

1. The CvMS is substantially equivalent in technological characteristics and intended use to the SphygmoCor SCOR-Px (K012487).

2. The CvMS's HRV feature is substantially equivalent to:

    a. Boston Medical Technologies' "BMT Anscore Health Management System" and its variations (K991831, K993875, and K010955);
    b. QMed, Inc.'s "Monitor One NDX" HRV analysis function (K972991); and
    c. Spacelabs, Inc.'s "Heart Rate Variability Software Option" (K950779).

E. Technological Characteristics Comparison

In the main, the CvMS and the SphygmoCor Px systems are substantially similar in design and technology. With the exception of the CvMS's HRV functionality, the intended uses of these two devices are the same. Like the SphygmoCor Px, the primary input signal to the CvMS comes from the a noninvasive tonometer which is calibrated via the brachial cuff. The software engine of the CvMS system is a somewhat modified version of that found in the SphygmoCor Px.

The CvMS has a new signal processing electronics module which is based upon the performance specifications for the SphygmoCor Px. Among other things, the CvMS's signal processing electronics module incorporates changes to permit powering the device via a computer USB and changes to permit HRV measurement. A detailed comparison of the technological similarities between these two devices can be found at Tab K.

AtCor Medical has identified three predicate devices for the CvMS's HRV option. Amongst the notable commonalities is the fact that all three of these predicate devices are modular software components of other devices that contain no mechanical components. As with the CvMS, both the Monitor One NDX and the ANScore measure HRV in response to controlled exercises. Likewise, these two devices analyze data gathered by a three-lead ECG connected to disposable snap-on electrodes to detect the electrocardiographic signals like the CvMS's HRV option. Like the CvMS's HRV option, all three of the predicates derive HRV measurements from a statistical analysis of electrocardiographic data using relatively simple mathematical functions. While the predicates vary slightly regarding what analyses are presented to the user, all of the analyses provided by the CvMS HRV option are also presented by one or more of these predicate devices.

F. Performance Testing

The entire system has also been tested to demonstrate compliance to the following standards:

- **IEC60601-1** (including its subparagraphs) Electro-Medical Equipment Safety (The biocompatibility testing clause of the standard was not applied since the only patient contact material is in the previously cleared Tonometer);
- **IEC60601-1-2** Collateral standard: Electromagnetic compatibility-Requirements and tests; and
- **AAMI EC13:2002** Cardiac monitors, heart rate meters, and alarms (substantial compliance only).

This testing has demonstrated that the CvMS meets electrical and environmental safety standards for safe use.

The CvMS has undergone hardware and software verification and validation testing to ensure that it complies with its performance requirements. In addition, comparison testing between the CvMS and the SphygmoCor Px demonstrated that the devices performed substantially the same with regard to their ability to provide a derived ascending aortic blood pressure waveform and a range of central arterial indices.

G. Conclusions

AtCor Medical has demonstrated the CvMS is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2007

AtCor Medical Pty. Ltd.
c/o Mr. Evan P. Phelps
Regulatory Counsel
1400 16th Street, NW Suite 400
Washington, DC 20036

Re: K070795
SphygmoCor® Cardiovascular Management System
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: Class II (two)
Product Code: DSK
Dated: August 6, 2007
Received: August 7, 2007

Dear Mr. Phelps:

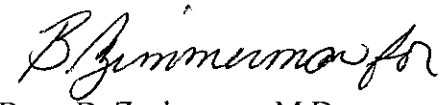
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070795

510(k) Number (if known): (Not yet assigned)

Device Name: SphygmoCor® Cardiovascular Management System

Indications for Use:

The SphygmoCor® Cardiovascular Management System (CvMS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The CvMS is used with a tonometer over a radial artery calibrated with a standard cuff blood pressure measurement. It is to be used on those patients where information related to ascending aortic blood pressure is desired but in the opinion of the physician, the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

The CvMS heart rate variability (HRV) option is intended for use in obtaining heart rate variability measurements in response to controlled exercises.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070795